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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,231	01/23/2004	Gerald T. Gourdin	HAU234 CIP2	8493

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,231	GOURDIN ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 30-33* is/are pending in the application.

4a) Of the above claim(s) *26-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/21/04 &1/23/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's arguments with respect to claims *1-25 and 30-33* have been considered but are moot in view of the new ground(s) of rejection.

The Status of claims :

Claims 1-33 are pending.

Claims 1-25 and 30-33 have been rejected.

Claims 26-29 have been withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,960,360 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim 1 discloses a broad limitation of a polymer resin which can include the prior art's brominated polystyrene resin.

U.S. Patent No. 6,960,360 B2 discloses the following claims:

1. A method of preparing a composition enriched in total phenols, comprising:

a) extracting a plant material known to contain phenolic compounds with an extraction solvent without adding bisulfite ions to form a crude extract comprising proanthocyanidins, anthocyanins, and non-phenolic compounds;

b) filtering said crude extract;

c) contacting said filtered extract with a brominated polystyrene resin, wherein said resin releasably adsorbs said phenols but does not retain said non-phenolic compounds;

d) washing said resin with a wash eluent to elute said non-phenolic compounds;

e) eluting the resin with a first eluent and collecting a first fraction containing phenols;

f) eluting the resin with a second eluent and collecting a second fraction containing phenols; and

g) isolating the fraction from step e) or step f) or combining said fractions from steps e) and f) to obtain a composition enriched in total phenols, wherein said composition has depleted levels of said non-phenolic compounds.

2. The method of claim 1, wherein said crude extract is prepared by extracting dried or fresh plant material(s) with an acidified extraction solvent.

3. The method of claim 2, wherein said acidified extraction solvent comprises an aqueous solution having between about 0–95% ethanol and between about 0–3% acid.

4. The method of claim 3, wherein said acid is sulfuric acid, acetic acid or hydrochloric acid.

5. The method of claim 2, wherein said acidified extraction solvent comprises an aqueous solution having between about 0–100% methanol and between about 0–3% acid.

6. The method of claim 5, wherein said acid is sulfuric acid, acetic acid or hydrochloric acid.

7. The method of claim 1, wherein said wash eluent contains at least 0.003% acid.

8. The method of claim 7, wherein said acid is acetic acid, hydrochloric acid or sulfuric acid.

9. The method of claim 1, wherein said first eluent comprises between about 50 and 70% ethanol in water and 0.003% acid.

10. The method of claim 9, wherein said acid is acetic acid, hydrochloric acid or sulfuric acid.

11. The method of claim 1, wherein said second eluent comprises between about 70 and 90% ethanol in water.

12. The method of claim 1, wherein said composition comprises between about 10-80% total phenols.

13. The method of claim 12, wherein said composition comprises at least 12% total phenols.

14. The method of claim 12, wherein said composition comprises at least 25% total phenols.

15. The method of claim 1, wherein said plant material is fruits and/or berries.

16. The method of claim 15, wherein said fruits and/or berries are selected from the group consisting of elderberries, blueberries, bilberries, blackberries, strawberries, cranberries, raspberries, plums, red currants, black currants, cherries, and grapes.

17. The method of claim 1, wherein step (a) further comprises adding pectinase to said crude extract.

18. The method of claim 17, wherein said pectinase is present in an amount between about 0 and 0.12% by weight of said plant material.

19. The method of claim 1, further comprising adding an excipient to said composition.

20. The method of claim 19, wherein said excipient is selected from the group consisting of preservatives, carriers, buffering agents, thickening agents, suspending agents, stabilizing agents, wetting agents, emulsifying agents, coloring agents and flavoring agents.

21. The method of claim 1, further comprising:

h) loading said composition from step e), said composition from step f), or said composition from step g) onto a low pressure vacuum liquid chromatography column packed with a reversed-phase lipophilic resin and collecting fractions that elute during said loading;

i) eluting said resin with water;

j) combining fractions from steps h) and i) to obtain a first composition enriched in polar proanthocyanidins; and

k) eluting said resin with increasing amounts of a polar organic solvent to obtain a second composition enriched in non-polar proanthocyanidins.

22. The method of claim 21, further comprising further purifying said first composition by reversed-phase preparative HPLC.

23. The method of claim 21, further comprising further purifying said second composition by gel filtration or preparative HPLC.

However, the instant invention differs from the prior art in that instant claim 1 discloses the broad limitation of a polymer resin unlike the prior art's brominated polystyrene resin.

Even so, the specification has described that the polymer resin does include brominated polystyrene resin (see page 5 ,lines 11-12); the brominated polystyrene resin has an unexpected property of binding proanthocyanidins and anthocyanins less tightly than non-brominated polystyrene resin, thereby allowing easy separation of phenolic compounds from undesired polar non-phenolic compounds (see page 15, paragraph 00102, lines 23-26).Therefore, it would have been obvious to the skilled artisan in the art to be motivated to select brominated polystyrene resin as the preferred resin among the polymer resins for the process.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-19 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabetta et al (U.S. 5,200,186) in view of Langston (U.S. 4,500,556) and S.O.R.I.(GB 1,235,379).

Gabetta et al discloses a commercial Vaccinium myrtillus extract contains 35 % of anthocyanosides (see col. 3 ,lines 45-46) , which can be used in a therapy in the pathology of capillaries and in the ophthalmology (see coil. 1 ,lines 12-15). Besides anthocyanosides and aglycones (see col. 1 ,lines 16-18), it may have mineral salts, common organic acids, and etc. (see col. 1 ,lines 27-30).

Furthermore, Gabetta et al teaches a method of preparing a high concentration of anthocyanosides from the fruits of Vaccinium myrtillus, Ribes nigrum, Vitis vinifera, Sambucus, and other plants (see col. 1, 11-12) in the following steps of :

a. extracting Vaccinium myrtillus fruits with 50 % aqueous methanol;

b. adding sodium bisulfite to the solution;

c. charging the solution to a non-polar polystyrenic resin;

d. washing the column with 8 liter of water, thereby eluting anthocyanosides;

e. concentrating the eluted aqueous solution under vacuum;

f. acidifying the aqueous solution with 1% hydrochloric acid solution;

g. extracting the aqueous solution with butanol;

h. washing the resultant solution with HCl solution; and

i. precipitating the solid and being dried under vacuum (see col. 3, example 1).

As a result of the process, the extract of anthocyanosides contains the following composition (%): delphinidin galactoside 13.20, delphinidin glucoside 15.00, delphinidin arabinoside 9.06, cyanidin galactoside 7.25, cyanidin glucoside 9.06, cyanidin arabinoside 4.41, petunidin galactoside 3.88, petunidin glucoside 9.07, petunidin arabinoside 1.94, peonidin galactoside 0.65, peonidin glucoside 3.45, peonidin arabinoside 0.24, malvidin galactoside 3.02, peonidin glucoside 9.06, peonidin arabinoside 0.95 (see col. 3 ,lines 30-40).

Furthermore, during the extracting step, a polar organic solvent immiscible with water is used(see col. 3 ,lines 30-40).

The instant invention ,however, differs from the Gabetta et al reference in that the two sequential eluting steps have been conducted ; the claimed resin is a protonated tertiary amine-substituted styrene divinylbenzene copolymer ; pectinase is present in the extract; the resultant composition comprises at least from 12 to 25 % total phenols.

Langston teaches a process of anthocyanin colorant from grape pomace in the following procedure:

a. contacting grape pomace with an aqueous extraction solvent containing HSO_3^- ions to extract an anthocyanin-bisulfite ion adduct;

b. removing the aqueous extraction solvent and undissolved solids from the grape pomace by filtration;

c. contacting the aqueous extraction solvent with a non-ionic adsorbent to adsorb the anthocyanin-bisulfite pigment complex;

d. washing the adsorbent to remove soluble sugar, organic acid and other water soluble non-pigmented material; and

e. eluting the anthocyanin from the adsorbent with an acidified organic solvent (see col. 2 ,lines 6-27).

In addition, during the process, the extract solution is filtered to remove undissolved solids in any convenient manner (see col. 3 ,lines 14-16) ; after filtering, the extract solution is contacted with a non-ionic adsorbent such as macroreticular styrene and divinylbenzene resin (see col. 3 ,lines 43-44).

Furthermore, S.O.R.I. discloses a process for extracting anthocyanines from certain berries and fruits by using extraction solvents, such as water ,methanol, ethanol or butanol or any mixture thereof (see page 2 , lines 32-35). During the process of yielding juice, pectinase can be added to the crushed fruits (see page 1, 39-45). Furthermore, the composition of the unpurified extract may contain 27 to 30 % of anthocyanins, traces of aglycone, monosaccharides, traces of pectins, and organic ions (see page 2 ,lines 55-68). The recovery of anthocyanins happens in the strong acidic medium, such as hydrochloric acid (see page 2 ,lines 75-81).

With respect to the two sequential eluting steps, this is directly related to the optimization of eluting steps. Furthermore, this does not have any patentable weight over the prior art reference. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to optimize the eluting steps by routine experimentations in order to enhance the process .

Concerning the use of the protonated tertiary amine-substituted styrene divinylbenzene copolymer in the process, Gabetta et al does indicate the broad use of

the non-polar polystyrenic resin and Langston expressly teaches the use of macroreticular styrene and divinylbenzene resin to which the protonated tertiary amine-substituted styrene divinylbenzene copolymer resin may be belonged. Furthermore, there is little difference between their respective functionalities during the purification processes. Furthermore, this does not have any patentable weight over the prior art reference. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to use as an alternative in order to enhance the process .

All three references have commonly shared the process of preparing the high concentration of anthocyanosides from the fruit by means of extraction and ion exchange resins. Gabetta et al does teach the general method of preparing the high concentration of anthocyanosides from the various fruits by extracting the fruits containing anthocyanines in the presence of the polar organic solvent by means of the non-polar polystyrenic resin. Langston does indicate that after filtering, the extract solution is contacted with the non-ionic adsorbent. And S.O.R.I. does point out that the pre-concentrated liquid and juice may be purified by means of ion exchange resins to form anthocyanin cations in the strong acidic medium. Therefore, it would have been obvious to the skillful artisan in the art to be motivated to incorporate Langston's filtration step prior to contacting ion exchange resins in the Gabetta et al process ,along with the use of S.O.R.I.'s strong acidic medium , thereby enhancing the purification process of anthocyanins. This is because the skilled artisan in the art would expect the

combined processes to increase the purity of the desired compound as well as to have a similar success as shown in the S.O.R.I. process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*** 6/24/06